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The clinical validation of the revised incontinence and patient satisfaction tools

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The clinical validation of the revised incontinence and patient satisfaction tools

Abstract

Powerpoint presentation presented at the Department of Health and Ageing, Canberra

Keywords

satisfaction, patient, incontinence, revised, tools, validation, clinical

Publication Details

J. E. Sansoni "The clinical validation of the revised incontinence and patient satisfaction tools",
Department of Health and Ageing, Canberra, 8 September 2011, (2011)



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The Clinical Validation of the Revised Incontinence and Patient Satisfaction Tools

Assoc Prof Jan Sansoni on behalf
of the project team



Refining Continence Measurement Tools

- Used the 2004 SAHOS data to assess the psychometric properties of the Urogenital Distress Inventory-6 and the Incontinence Severity Index
- Assessed the psychometric properties of the Wexner Faecal Continence Grading Scale and the other faecal items included in the survey
- Psychometric analyses of the data used both Classical Test Theory and Modern Test Theory (IRT) approaches
- Revised 5 item measures of incontinence were derived
 - Revised Urinary Incontinence Scale
 - Revised Faecal Incontinence Scale

Validating Tools in Clinical Settings

- This project, funded by DoHA, assessed these tools in clinical settings – 11 clinics across 4 states
- Descriptive statistics, reliability, factor structure, correlations with other measures are examined
- Also examined type of treatment variables – continence advising, physiotherapy, surgical interventions and responsiveness to change over time

Revised Urinary Incontinence Scale

Do you experience and how much are you bothered by:

- Urine leakage related to the feeling of urgency?
- Urine leakage related to physical activity, coughing or sneezing?
- Small amounts of urine leakage?

Responses = not at all, slightly, moderately, greatly (0-3)

- How often do you experience urine leakage?

Responses = never to every day/night (0-4)

- How much urine do you lose each time?

Responses = none, drops, small splashes, more (0-3)

Scores range from 0-16

RUIS : Descriptive Statistics

Females

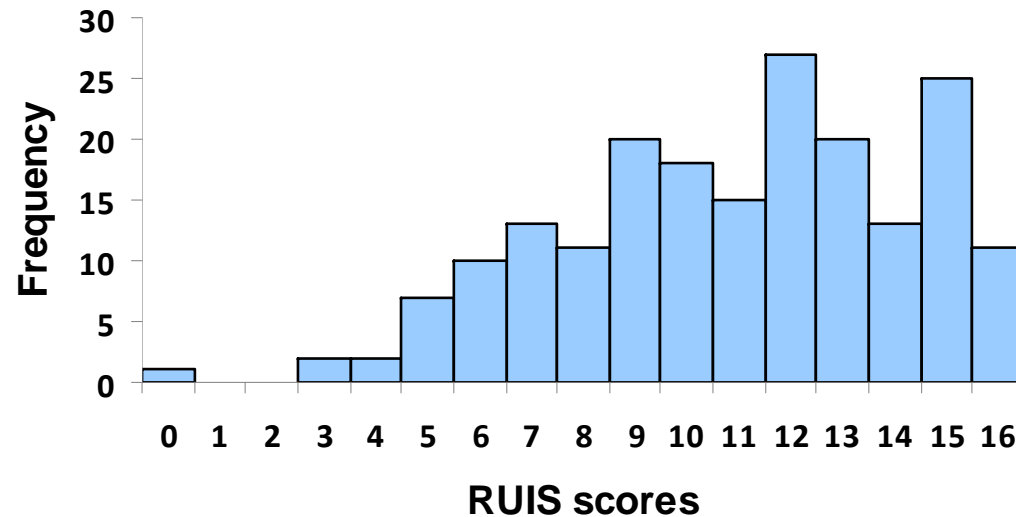
	N	Mean	SD	Actual Range	
RUIS-SAHOS	1715	2.48	3.33	0	16
RUIS Clin PS Retro*	163	11.56	3.31	1	16
RUIS Clin Prosp.*	167	10.9	3.18	3	16

Males

	N	Mean	SD	Actual Range	
RUIS-SAHOS	1206	0.73	1.97	0	16
RUIS Clin Prosp.*	28	11.07	4.18	0	16

** = Clinical samples at pre-treatment*

RUIS Pre-treatment Score Distribution (Clinical Sample)



N = 195; Mean 10.92; SD 3.33; Mode = 12; Median = 11

Males = 11.07; Females 10.90

Reliability Estimates RUIS Cronbach's Alpha

Data Source	Pre-treatment	Post-treatment
SAHOS all-RUIS	0.91	NA
PS Retro study (women)	NA	0.85
Current Study-UI	0.73*	0.90
Current Study-all	0.84	0.91

*Pre-treatment alpha for UDI-6 = 0.64; ISI = 0.54

Factor Structure

- Explains 49% of the variance – uni-dimensional

	Factor
<i>Items</i>	1 (49%)
RUIS1-urge	0.64
RUIS2-stress	0.67
RUIS3-leak small amounts	0.80
RUIS4-leak frequency	0.72
RUIS5-leak volume	0.64

N = 195 UI patients; replicated all patients (N =255) – variance explained 62%

Factor Structure

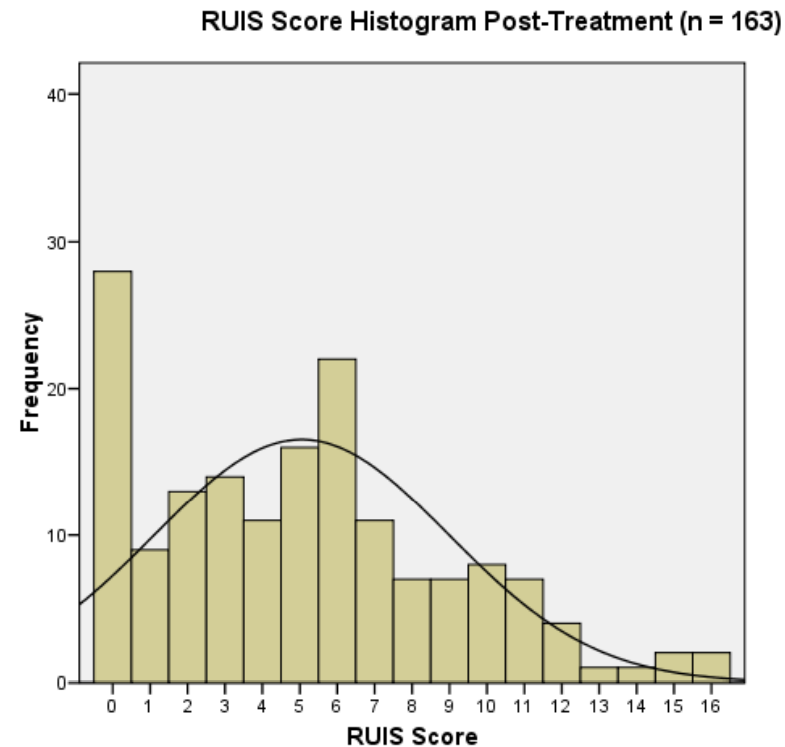
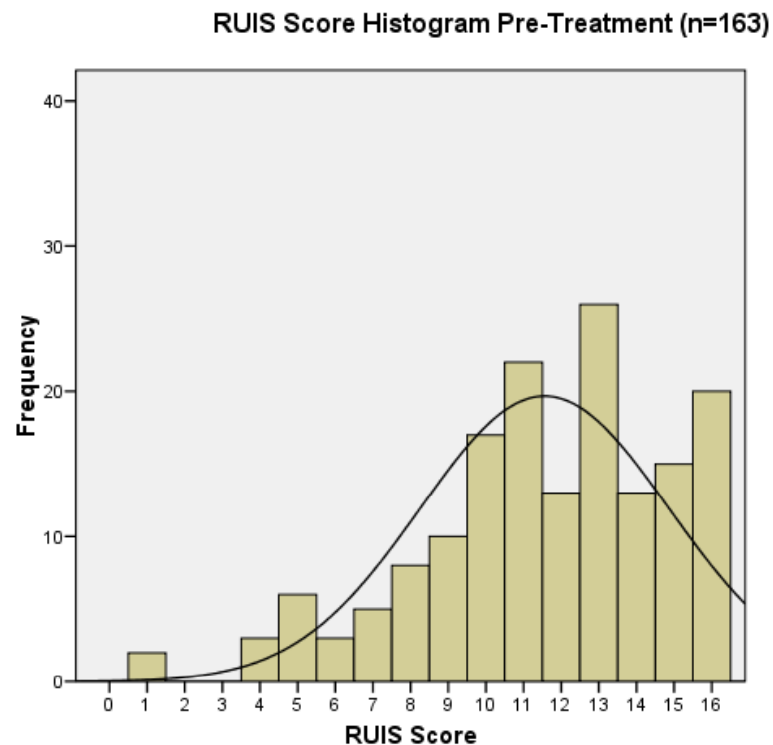
Rotated Factor Matrices for a Larger Set of Urinary Incontinence Items

		Community Survey 2006 N = 2921		Clinical Survey 2011 N = 195	
	<i>Scale</i>	<i>Factor/Component</i>		<i>Factor/Component</i>	
		1	2	1	2
Freq Urination		0.48	0.49	0.41	0.54
Urgency Leakage	RUIS1	0.74		0.60	0.42
Stress Leakage	RUIS2	0.82		0.67	
Leak Small Amount	RUIS3	0.85		0.77	
Emptying Bladder			0.76		0.76
Pain Lower Abdominal			0.75		0.71
Leakage Frequency	RUIS4	0.89		0.71	
Leakage Amount	RUIS5	0.89		0.66	

Note: Principal Components Analyses with Varimax Rotation were employed in both studies.

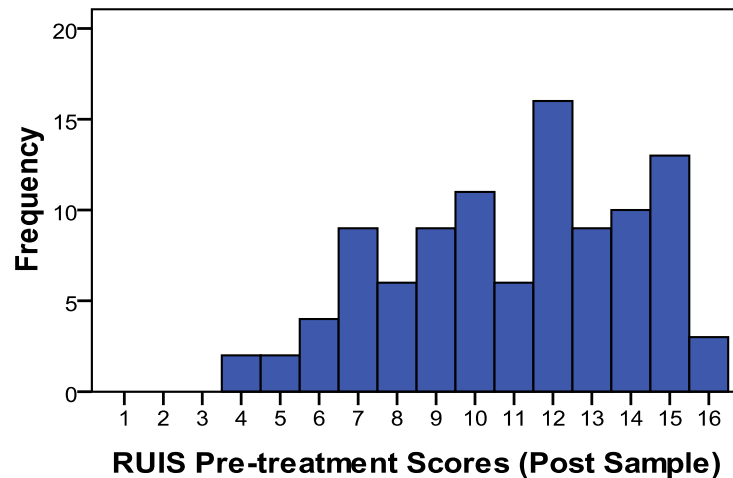
RUIS: Before and After Treatment

Patient Satisfaction (PS) Study



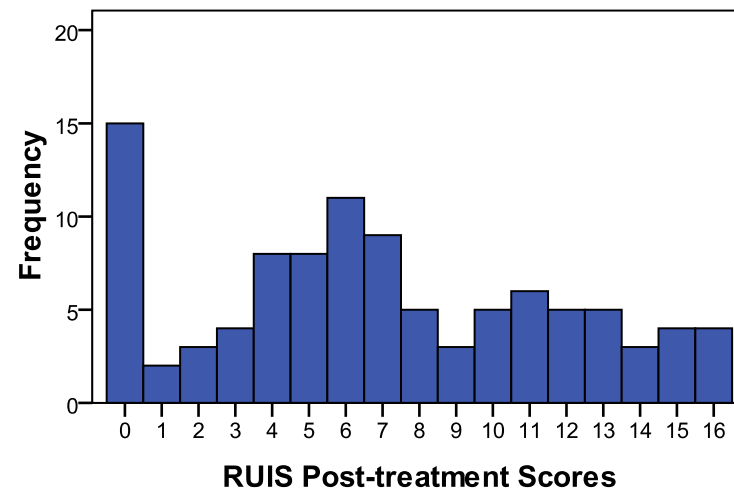
RUIS: Before and After Treatment

Pre-Treatment



Mean = 11.02, SD = 3.08, N = 100

Post-Treatment



Mean = 6.95, SD = 4.77, N = 100

At follow up the mean RUIS score was **6.95**, (SD = 4.77, N = 100). For females the mean was 6.91 and for males the mean was 7.21.

Examination of pre-post scores revealed a statistically significant improvement of **4.07** points (SD = 4.76, N = 100) (paired t-test, $t = 8.56$, $df = 99$, $p < 0.01$).

RUIS: Change with Treatment: Pre and Post cases

Study	Mean	SD	N
PS PRE (retro)	11.81	3.81	163
PS POST	4.93	3.94	163
Then-test mean change score	6.29	4.78	163
Current study Pre (females)	11.02	3.15	86
Current study Post (females)	6.91	4.83	86
Mean change score	4.12	4.88	86

RUIS: Change with Treatment

Study	Change type*	N	%
PS Retro	% report improvement	144	85.7
	% report no change	13	7.7
	% report worse	11	6.5
Current Study	% improved	77	77.0
	% no change	5	5.0
	% worse	18	18.0

Improvement = +1 or more; Worse = -1 or more

Effect of Treatment

- For all treatment groups RUIS scores improved significantly (4.07) with treatment
- There was a significant difference by type of treatment. Mean improvement for CA = 2 (n = 13); for Physiotherapy = 3.09 (n = 55) and for Surgery = 7.07 (n = 29)
- An analysis of RUIS change by Patient Global Rating of Improvement suggests the Mean Clinically Important Difference (MCID) for patients is estimated at 2 RUIS change scores.

Associations with Other Measures

	UDI-6	ISI	ICIQ-UI	Wei ISI	IIQ	PR Severity	CR Severity
RUIS* (Pre)	0.76	0.76	0.74	0.72	0.53	0.62	0.37

* All correlations $p < 0.01$

Clinical Severity Ratings – RUIS mean score for mild = 9.22 and for moderate and severe = 11.87 (F = 33.80; df 1,192; $p = 0.000$). **Patient Severity Ratings** – RUIS mean score for mild = 8.36; moderate = 11.60; severe = 14.03 (F 58.65; df 2, 191; $p = 0.000$)

Daily Pad Use – RUIS mean for 1 or less = 9.02, for 2 or more = 12.60 (F Welch = 78.33; df 1,171.06; $p = 0.000$). **Pad Use Size** – RUIS mean for no/thin pad = 9.21; medium pads = 12.00, large pads = 13.57 (F = 38.56; df 2, 191; $p = 0.000$)

ICIQ number of symptoms severity index – RUIS mean scores for 2 or less symptoms = 8.60; 3-4 symptoms = 11.46, 5 or more symptoms = 13.21 (F Welch = 43.84; df 2, 125.42; $p = 0.000$)

RUIS scores were also higher for those having **surgical treatment** and for those experiencing **double incontinence**

Suggested Cut Points

Based on the sample distributions and clinician and patient ratings the following cutpoints for interpretation are suggested:

- 0-3: no urinary incontinence or extremely mild or occasional incontinence symptoms
- 4-8: mild urinary incontinence
- 9-12: moderate urinary incontinence
- 13-16: severe urinary incontinence (scores of 15 -16 could be considered very severe)
- For screening we suggest a score of 4 would warrant further assessment.

RUIS: Reliable, Valid and Responsive

- The internal consistency reliability estimate is considered adequate to good for clinical samples (0.73 - 0.84 Pre and 0.91 Post) and better than other short measures UDI-6 and ISI
- Retest Reliability is good 0.80 (ICC)
- The RUIS demonstrates good responsiveness to change as a result of treatment
- The RUIS has an appropriate internal structure, correlates appropriately with other UI measures and discriminates well between other clinical indicators of incontinence severity (validity)

Revised Faecal Incontinence Scale

- Do you leak, have accidents or lose control with solid stool? (Wexner)
- Do you leak, have accidents or lose control with liquid stool? (Wexner)
- Do you leak stool if you don't get to the toilet in time?
- Does stool leak so that you have to change your underwear?
- Does bowel or stool leakage cause you to alter your lifestyle? (Wexner)

Response Categories: Never/ Rarely, i.e. < once in the past four weeks/ Sometimes, i.e. < once a week, but > once in the past four weeks/ Often or usually, i.e. < once a day but > once a week/ Always, i.e. > once a day or whenever you have a bowel movement

Item scores range from 0-4 and the Scale Score ranges from 0-20

RFIS: Psychometric Properties & comparison with RUIS

Females

	N	Mean	SD	Actual Range	
RFIS-SAHOS	1715	0.43	1.56	0	18
RFIS Clin Prosp*	51	9.76	4.86	0	20
RUIS Clin Prosp*	167	10.90	3.33	3	16

Males

	N	Mean	SD	Actual Range	
RFIS-SAHOS	1202	0.26	1.04	0	12
RFIS-Clin Prosp*	10	9.10	3.6	3	16
RUIS Clin Prosp*	28	11.07	3.74	0	16

** = Clinical samples at pre-treatment*

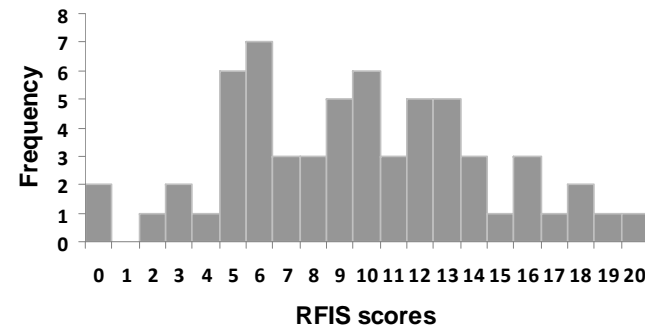
RFIS Distributions

RFIS pre-treatment scores (all)

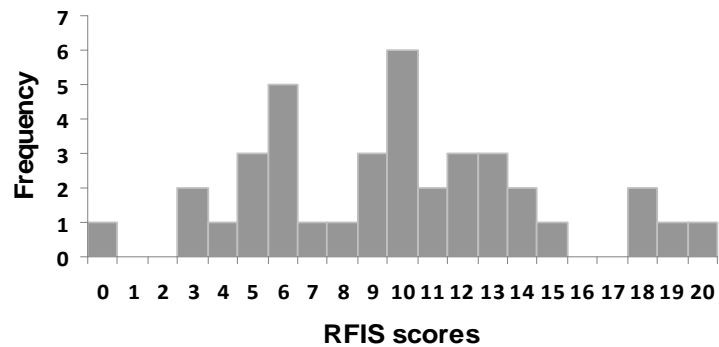
N = 61

Mean = 9.66

SD = 4.66

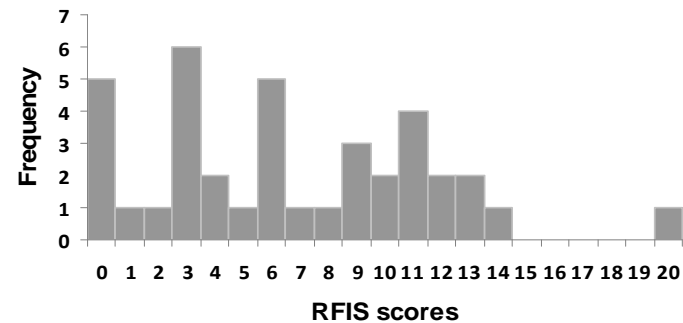


RFIS pre-treatment (post sample)



N = 38, Mean = 9.79, SD = 4.68

RFIS post-treatment

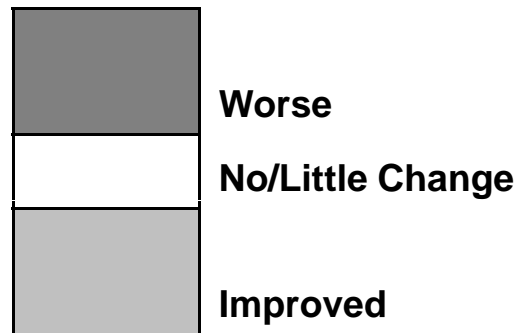
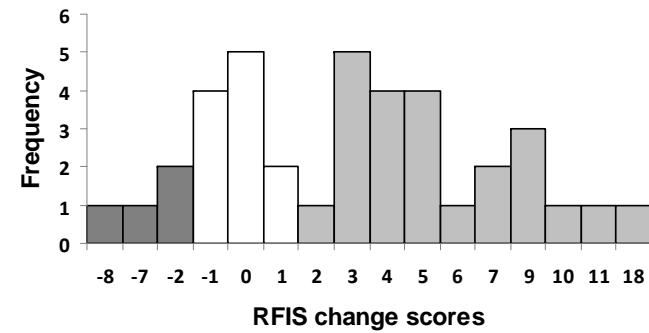
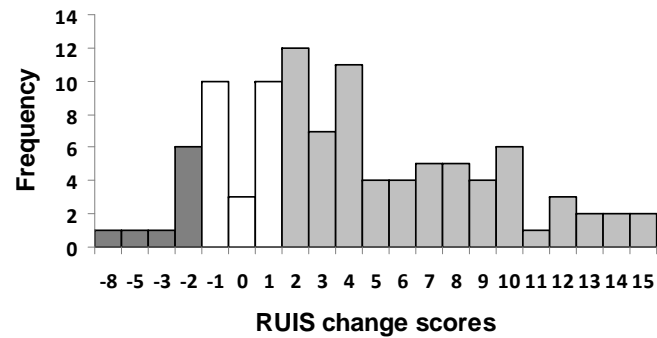


N = 38, Mean = 6.68, SD = 4.82

Faecal Incontinence

- There was a an improvement of 3.11 points (paired t-test, $t = 3.89$, $df = 37$, $p = 0.000$). RFIS the most responsive measure. No difference in improvement between surgical and conservative treatments – all improved.
- The internal consistency reliability (ICR) for the RFIS pre-treatment is 0.78 (faecal sample). By comparison pre-treatment alphas for Wexner = 0.65 and St Marks = 0.66 which are considered inadequate. The ICR of RFIS = 0.91 (all patients).
- Retest reliability is good = 0.80 (ICC)
- RFIS scores discriminate by clinician and patient severity ratings, pad use and size, duration of symptoms and other severity indices. High correlations with other FI measures.
- Factor structure suggest RFIS is a uni-dimensional scale - the general faecal incontinence factor explains 54% of variance

RUIS & RFIS Change Scores



Suggested Cut Points

Based on the sample distributions, clinician and patient ratings and comparison to other severity indicators the following cut points for interpretation are suggested

- 0-3: no faecal incontinence or extremely mild or occasional incontinence symptoms
- 4-9: mild faecal incontinence
- 10-14: moderate faecal incontinence
- 15-20: severe urinary incontinence (scores above 16 could be considered very severe)
- For screening we suggest a score of 4 would warrant further assessment.

Conclusions

- Data indicates both the RFIS and the RUIS have good psychometric properties (reliability, validity) and are sensitive to detecting change in patients' incontinence status (responsiveness)
- The RUIS and RFIS are very short and simple to use and provide reliable estimates of the extent of the patient's incontinence and the extent of their improvement from treatment
- Good for quality improvement - use in routine practice should be encouraged – an online collaboration?

Patient Satisfaction

- Hawthorne (2006) **Review of patient satisfaction measures** for continence services and treatments

Reviewed instruments

- Client Satisfaction Questionnaire (CSQ-18) (Larsen, et al. 1979) (generic)
- Consultation Satisfaction Questionnaire (Consult SQ) (Baker, 1990) (generic)
- Patient Satisfaction Index (PSI) (Guyatt, et al. 1995) (generic)
- Genito-Urinary Treatment Satisfaction Scale (GUTSS) (Hawthorne and Hamer, 2000) (condition specific)

Theory

“Patient satisfaction may be considered to be one of the desired outcomes of care, even an element in health status itself. An expression of satisfaction or dissatisfaction is also the patient’s judgment on the quality of care in all its aspects, but particularly as concerns the interpersonal process.”

(Donabedian, 1998, p. 1746)

- Seven key domains: effectiveness, information, technical skill, participation, relationship, access & facilities, satisfaction general.

Original Patient Satisfaction Study

- Post treatment design (*Then-Test Procedure*)
- Survey – 4 patient satisfaction measures (CSQ-18, Consult SQ, PSI, GUTSS), incontinence symptoms, plus other items about treatment (e.g. expectations).
- St George Hospital, Sydney and Royal Women's Hospital, Melbourne (and associated private clinics)
- Women only
- Urinary patients
- Treatments = surgery or physiotherapy
- N = 178

Results

- An examination of the psychometric properties of the four instruments found some evidence of item redundancy, response bias and poor responsiveness.
- Non-responsive & poorly worded items were deleted and the remaining items (n = 49) were used to develop a pooled patient satisfaction estimate.
- Used Item Response Theory (IRT) to examine and select the items with the best fit with the pooled patient satisfaction estimate. In this iterative analysis we were looking for the best fitting model consistent with the 7 domains of patient satisfaction. A 7 item draft SAPS was developed

Summary

- The draft SAPS had an excellent coverage of patient satisfaction model and was a strong uni-dimensional scale (Loevinger H = 0.55).
- The draft SAPS was more sensitive than any other instrument to the pooled patient satisfaction estimate.
- Internal consistency reliability (Cronbach's alpha) = 0.86
- The draft SAPS correlated well with other measures of patient satisfaction and with other indicators of treatment outcomes – most improved had higher satisfaction scores

Current Study

- Pre and post treatment design (prospective study)
- Survey - continence symptoms, clinical ratings, quality of life measures and satisfaction items
- Tested some changes to the wording of the original SAPS items e.g. replacing 'how happy' with 'how satisfied' for two items
- Tested the order of response categories (very satisfied – very dissatisfied) for some items
- Tested some additional Qs – re success and outcomes of treatment, expectations and patient global improvement

Short assessment of patient satisfaction (SAPS)

Effectiveness: How satisfied are you with the effect of your treatment ?

Information: How satisfied are you with the explanations the doctor or other health professional has given you about the results of your treatment ?

Technical Skill: The doctor or other health professional was very careful to check everything when examining you?

Participation: How satisfied were you with the choices you had in decisions affecting your health care ?

Relationship: How much of the time did you feel respected by the doctor or other health professional ?

Access & facilities: The time you had with the doctor or other health professional was too short?

Satisfaction: Are you satisfied with the care you received in the hospital or clinic ?

Preliminary Data - Summary Statistics 2011

Study 1	SAPS Total %		
Group	Mean	SD	N
Women - Urinary	82.52	15.12	176

Study 2	SAPS Total %		
Group	Mean	SD	N
Women - Urinary	76.86	18.29	86
Men - Urinary	81.11	16.07	14
Women - Faecal	80.75	17.04	31
Men - Faecal	84.82	7.57	8
All incontinence	78.43	17.32	139

Cronbach's alpha = 0.80-0.85

SAPS Data

Figure 2: SAPS score distribution

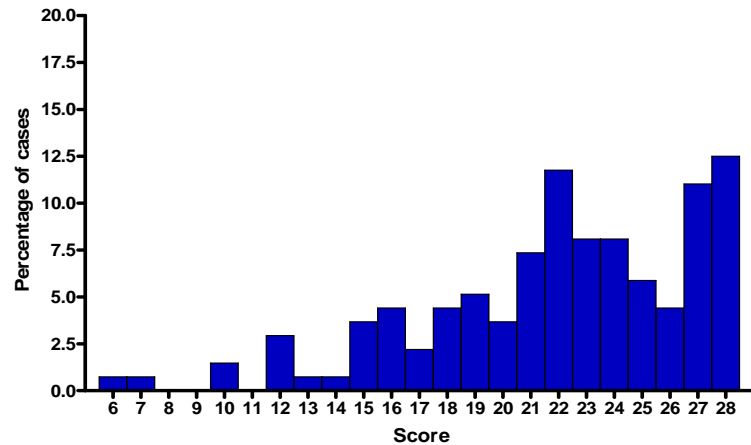
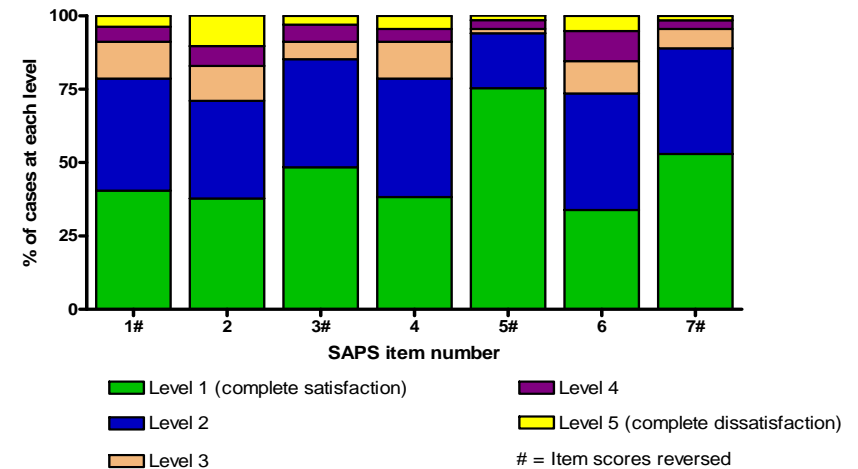


Figure 5.1: SAPS item data distribution



0-10 very dissatisfied; 11-18 dissatisfied; 19-26 satisfied; 27-28 very satisfied.

Mean 21.96, SD 4.85 (N = 139 all incontinence patients)

Summary: SAPS

- Statistically significant differences in mean SAPS scores by type of **incontinence treatment** (surgical patients more satisfied), **clinician and patient rated severity** at post-treatment (normal/mild more satisfied) and **post-treatment general health status** (fair/poor health least satisfied)
- No significant differences by gender, age group, educational attainment or incontinence type
- SAPS demonstrates good discriminant validity
- Easy to use for quality improvement activities

Other Activities

- Burden of disease – UI \$17 billion p.a.; FI \$8 billion p.a.- first estimates for faecal burden of disease
- Issue of whether you include mild cases (75%)
- Faecal Cost Of Illness – total personal costs not related to severity (as costs of investigation are fixed and uniform regardless of severity). Costs for pads and creams significantly related to severity. Total patient expense p.a. = @\$609; total incontinence expense (patient, health fund and govt. = @1,400 p.a. per patient.)

IMPACT

SF-36 Profiles Scores at Pre-treatment



Recommendations

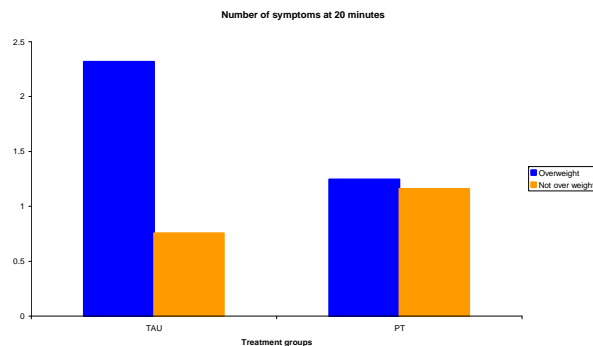
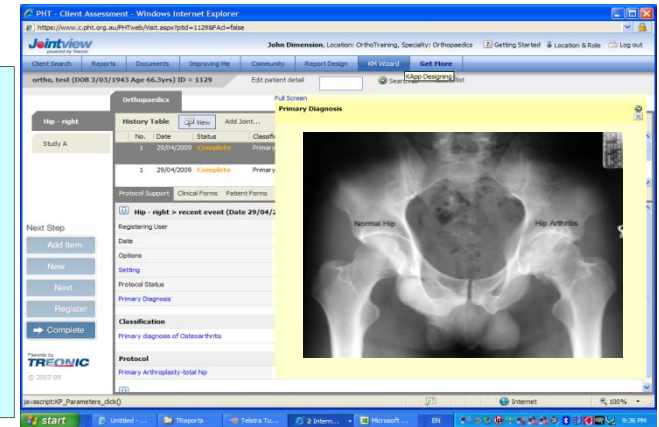
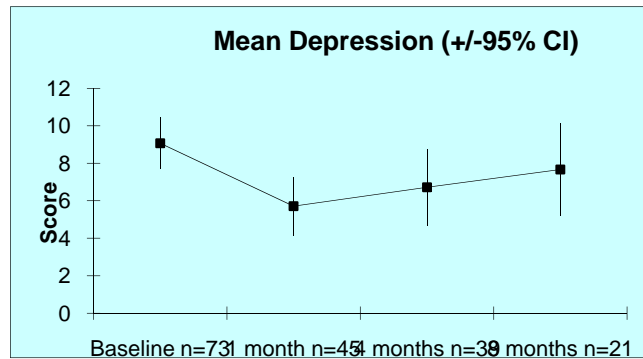
- Facilitate use in routine practice with an **online collaboration** – outcomes monitoring
- Online collaboration – patient management and monitoring - can also address research gaps
- Cultural adaptation of tools needed for those from indigenous and CALD backgrounds; proxy versions for children and frail elderly
- ALSWH – 5000 cases, now 2 time points for RUIS – worthwhile to analyse this data

DiscoverQuick

Overwhelmingly enthusiastic
response

Neonatology
Pain management
Gastroenterology
Orthopaedics/Cardiology
Diabetes Educators Assoc.
Community Living Project
Arthritis ACT, SA, Qld, Tas
Academic medicine unit
Endometriosis (gynaecology)
Respiratory and Sleep Medicine
Mental health (working towards a start)
Rheumatology (under discussion)
Registrar training (under discussion)
Anaesthetics (under discussion)

Individual Monitoring, Group Comparisons



Minimisation Group	Treatment Allocation	Count
< 7 years old & Not Overweight	Treatment As Usual	2
	Prescribed Treatment	4
< 7 years old & Overweight	Treatment As Usual.	2
7 + years old & Not Overweight	Treatment As Usual..	17
	Prescribed Treatment.	14
7 + years old & Overweight	Treatment As Usual...	7
	Prescribed Treatment..	6
Grand Total		52

Discoverquick.com - Windows Internet Explorer

https://www.c.pht.org.au/PHTweb/Visit.aspx?ptid=11743&FAcl=false

DiscoverQuick.com

Ali Khazaie, Location: Treonic, Specialty: User-Site0

Client Search

Reports

Documents

Upload

Improving Me

Community

Report Design

Incont, Flo (DOB 3/03/1941 Age 70.5yrs) ID = 11743

Edit client detail

Incontinence

Management Table

View

Add Item...

Delete

Email

No.	Date	Status	Classification
1	06/09/2011	complete	Registered

Protocol Support

Collection Forms

Client Forms

Notes ...

Reports

Incontinence > recent event (Date 06/09/2011)

Form Name

RFIS

RUSD

SAPS

Click on a Form to enter informaton. To start a New event click on Complete

Next Step

Add Item

New

Next

Register

Complete

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Discoverquick.com -- Webpage Dialog

https://www.c.pht.org.au/PHTweb/Dialogs/Collectionform.aspx?insId=919&insName=RFIS&insAuditTrailId=196751&ptid=11743&insStatusId=11&insEditable=True&insClr=I&vis

RFIS (created on 06/09/2011)

Client ID = 11743 (DOB 3/03/1941)

Print

Response

Copy

Go Down

Revised Faecal Incontinence Scale (RFIS)

Do you leak, have accidents or lose control with solid stool?

never

Rarely i.e. less than once in the past four weeks

Sometimes i.e. less than once a week, but once or more in the past four weeks

Often i.e. less than once a day, but once a week or more

Always i.e. once or more per day or whenever you have a bowel movement

Do you leak, have accidents or lose control with liquid stool?

never

Rarely i.e. less than once in the past four weeks

Sometimes i.e. less than once a week, but once or more in the past four weeks

Often i.e. less than once a day, but once a week or more

Always i.e. once or more per day or whenever you have a bowel movement

Do you leak stool if you don't get to the toilet in time?

never

Rarely i.e. less than once in the past four weeks

Sometimes i.e. less than once a week, but once or more in the past four weeks

Often i.e. less than once a day, but once a week or more

Always i.e. once or more per day or whenever you have a bowel movement

Does stool leak so that you have to change your underwear?

never

Rarely i.e. less than once in the past four weeks

Sometimes i.e. less than once a week, but once or more in the past four weeks

Often i.e. less than once a day, but once a week or more

Always i.e. once or more per day or whenever you have a bowel movement

Does bowel or stool leakage cause you to alter your lifestyle?

never

Rarely i.e. less than once in the past four weeks

Sometimes i.e. less than once a week, but once or more in the past four weeks

Often i.e. less than once a day, but once a week or more

Always i.e. once or more per day or whenever you have a bowel movement

Close

Save & Close

Save

Next

Clear All

https://www.c.pht.org.au/PHTweb/Dialogs/Collectionform.aspx?insId=919&insName=RFIS&insAuditTrailId=196751&ptid=11743&insStatusId=11&insEditable=True&insClr=I&vis

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https://www.c.pht.org.au/PHTweb/Dialogs/Collectionform.aspx?insId=918&insName=RUIS&insAuditTrailId=196752&ptid=11743&insStatusId=11&insEditable=True&insClr=I&vis

RUIS (created on 06/09/2011)

Client ID = 11743 (DOB 3/03/1941)

Print

Response

Copy

Go Down

Revised Urinary Incontinence Scale (RUIS)

Do you experience and if so how much are you bothered by:

Urine leakage

Not at all

Slightly

Moderately

Greatly

Urine leakage related to physical activity, coughing or sneezing

Not at all

Slightly

Moderately

Greatly

Small amounts of urine leakage (drops)

Not at all

Slightly

Moderately

Greatly

How often do you experience urine leakage

Never

Less than once a month

A few times a month

A few times a week

Every day and/or night

How much urine do you lose each time?

None

Drops

Small splashes

More

Close

Save & Close

Save

Next

Clear All

Refresh

Design

Close Design

Reports

1

DiscoverQuick.com

Treonic - ReportClientDisplay -- Webpage Dialog
 https://www.c.pht.org.au/PHTweb/dialogs/ReportClientDisplay.aspx?

Reports Please select from the knowledge library below and then select from the reports available
 Knowledge Library: SiteLibraryForAll_10153_1

Reports Available

Report Detail

Conditions/Trials:

Collection forms:

Optional - select specific client ID and/or a date range
 Client ID: 11743 Start date: DD / MM / YYYY End date: DD / MM / YYYY Clear

Open Report

3 Month Follow-Up Report

Name: (blank)
 Date: 08/08/2011

Number of bad pain days last week: 0 days

Hours of bad pain on those days: 0 hours

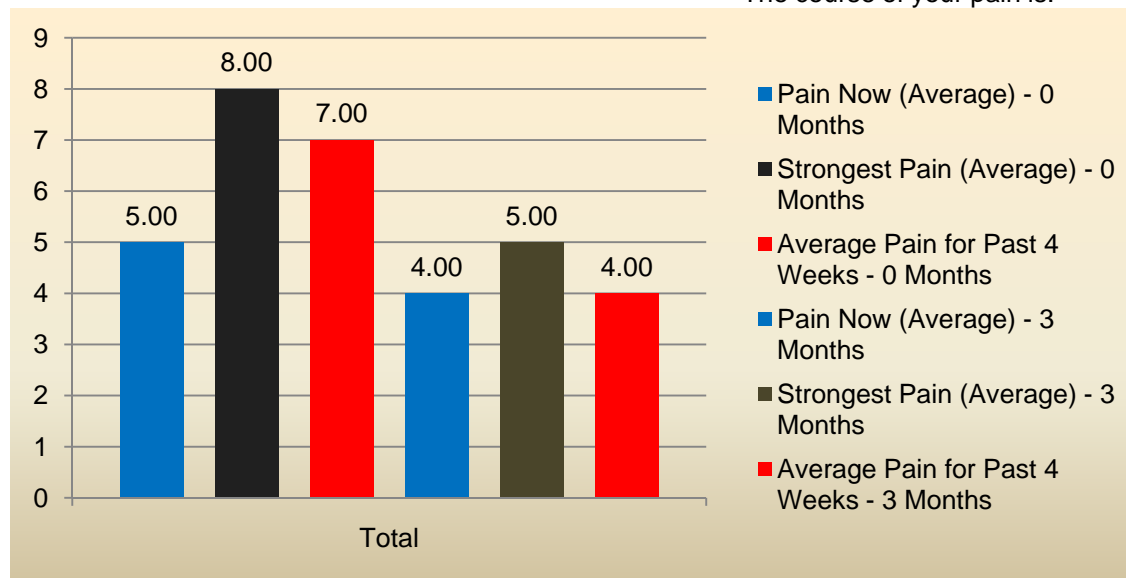
How would you assess your pain **now**, at this moment? (0 - none to 10 - max) 4

How strong was the **strongest** pain during the past 4 weeks? (0 - none to 10 - max) 5

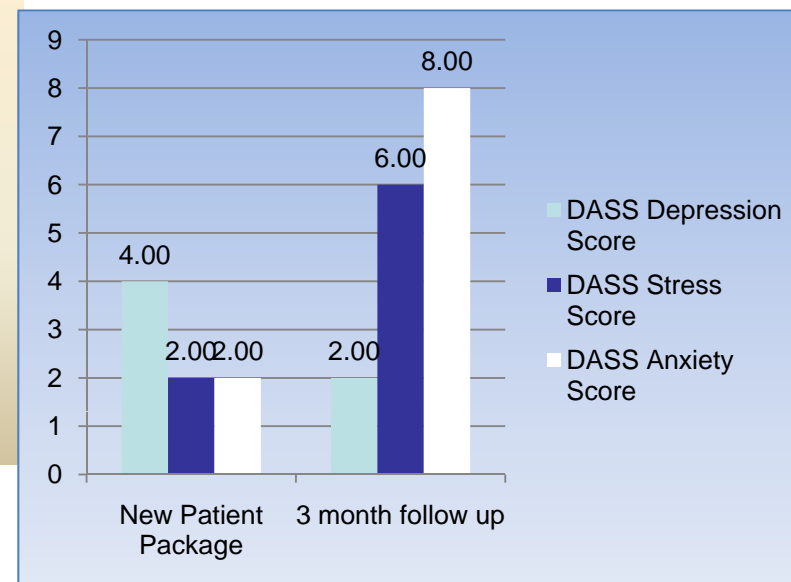
How strong was the pain during the past 4 weeks on **average**? (0 - none to 10 - max) 4

Your pain at its least in the past 4 weeks: 3
 (0 = No Pain & 10 = Pain as bad as you can imagine)

The course of your pain is: Persistent pain with slight fluctuations



DiscoverQuick.com



What's happened?

Canberra Hospital
Westmead Hospital
Royal Brisbane Hospital



Best method to wean stable pre-term babies off Continuous Positive Airway Pressure (CPAP)

- Used DQ's randomisation module in the scientific tool kit
- **Results:**

Most unexpected method (basically straight off CPAP) produced:

- **3 times less Chronic Lung Disease (9% vs 30%)**
- 2 weeks on average less time in hospital
- DRG \$ saving of \$7,000 per baby at TCH or
- **\$504,000 per year at TCH**
- Peer review publication in train
- Guidelines are now being developed
- Long-term cohort study, with nested RTCs next step
- **Savings multiplied if across sites**

Benchmarking

Imagine a
much larger
sample..

Clinic Type		RUIS Pre	RUIS Post	RUIS Change
1 Conservative (9 = CA)	Mean	10.20	7.70	2.50
	N	10	10	10
	Std. Deviation	2.78	4.67	3.57
2 Physio	Mean	10.92	8.03	2.89
	N	36	36	36
	Std. Deviation	3.38	4.61	4.01
3 Surgery	Mean	11.07	5.29	5.79
	N	14	14	14
	Std. Deviation	3.56	4.73	5.79
4 Conservative (CA = 6 PH = 7)	Mean	11.46	10.15	1.31
	N	13	13	13
	Std. Deviation	3.36	3.28	2.81
5 Surgery	Mean	12.00	3.73	8.27
	N	15	15	15
	Std. Deviation	2.04	5.44	5.66
6 Physio	Mean	10.88	5.25	5.63
	N	8	8	8
	Std. Deviation	2.42	1.83	3.11
Total	Mean	11.10	6.98	4.13
	N	96	96	96
	Std. Deviation	3.07	4.81	4.84